

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

IN RE: VIAGRA PRODUCTS
LIABILITY LITIGATION

MDL No. 1724
Judge Paul A. Magnuson

This document pertains to:
ALL CASES

EXPERT REPORT OF GERALD McGWIN, JR., MS, PhD
URSUNT TO FEDERAL RULE OF
CIVIL PROCEDURE 26(a)(2)(B)

Expert Witness Report of Gerald McGwin, Jr., M.S., Ph.D.

I. Personal Information

My name is Gerald McGwin and I am currently an associate professor in the Department of Epidemiology at the University of Alabama at Birmingham School of Public Health where I also serve as the Director of the Ph.D. program. I have secondary appointments in the Departments of Ophthalmology and Surgery at the University of Alabama at Birmingham School of Medicine. I received an M.S. degree in Health and Social Behavior from Harvard University in 1995 and a Ph.D. degree in epidemiology from the University of Alabama at Birmingham in 1998.

My research interests include injury epidemiology and ophthalmic epidemiology though I also work in the areas of systemic lupus erythematosus and epidemiologic methods. I regularly present the results of my research at other institutions and at national epidemiology, ophthalmology and trauma care meetings. I am being compensated at a rate of \$200 per hour for reading and evaluating the material associated with this case, \$300 per hour for data collection and management activities, and \$400 per hour for statistical analyses.

I have not testified as an expert at trial or by deposition within the preceding four years.

Since 1998 I have authored or co-authored over 200 peer reviewed manuscripts. I am an Associate Editor for the *American Journal of Epidemiology* and regularly review manuscripts for over a dozen clinical, public health and epidemiology journals.

I serve as a grant reviewer for the National Institutes of Health among other local, national and international organizations.

I currently teach three courses a year, two of which are Ph.D. level courses focused on the design and analysis of case-control and cohort studies; I also teach an introductory course on the principles of epidemiology.

A copy of my curriculum is attached and provides greater detail on my professional experience.

II. Epidemiology and Causality

Prior to addressing the issue at hand, it is first important to define epidemiology and discuss how it can and cannot provide evidence of cause and effect relationships.

Epidemiology is the study of the distribution and determinants of diseases in populations. Epidemiology can be descriptive, for example, quantifying the rate of lung cancer in a defined population or it can be etiologic, investigating characteristics risk factors for lung cancer. Epidemiologists collect information on disease occurrence (or lack thereof) and potential risk factors of interest (often called exposures) using a variety of valid, reliable, and reproducible techniques. How and which of these techniques are employed is governed by the application of

specific study designs in conjunction with careful consideration of the disease in question, specifically issues related to natural history. Specific hypotheses of interest are tested using statistics that are selected and applied with consideration of the specific study design being utilized. Though diverse, nearly all such statistical analyses have a common goal of quantifying the existence of an association between a specific risk factor and disease. However, the interpretation of a quantified exposure-disease relationship must be done in light of any potential threats to a study's validity. Flaws in a study's design or analysis can introduce specific biases that can obscure a relationship when one truly exists and vice versa.

Epidemiology is an observational science, thus even devoid of threats to validity it cannot prove (or disprove) causality. Establishing whether a hypothesized exposure-disease association reflects a true cause-effect relationship requires a diversity of information and the results of epidemiologic studies represent one, albeit important, such element. The criteria frequently used to determine whether the available information supports or refutes causality were described by Sir Austin Bradford Hill in 1965. The application of Hill's nine criteria or tenets serve as a benchmark against which scientific and common sense evidence are measured; the result being a judgment as to whether a particular exposure-disease relationship is indeed causal.

II. Sildenafil Citrate (Viagra) and Nonarteritic Anterior Ischemic Optic Neuropathy (NAION): A Causal Relationship?

Hill's criteria will be used to provide perspective on the etiology of NAION as it pertains to the use of Viagra. The discussion below will focus primarily on the published, peer-review epidemiologic and clinical evidence regarding this relationship.

II.a. Strength of Association: In epidemiologic studies strength of association is quantified using a variety of measures that, as mentioned above, are related to the specific epidemiologic study design being used. In general, these measures quantify the risk or rate of disease among those with a particular exposure compared to the risk (or rate) among those without the exposure. In contrast certain study designs compare the odds of exposure among those with and without the disease in question. With respect to the association between Viagra and NAION, there have been two published, peer-reviewed studies. McGwin et al. conducted a matched case-control study and reported an odds ratio (OR) of 1.75 with a 95% confidence interval (CI) of 0.48 to 6.30. Thus, the odds of Viagra use were 75% greater among men with NAION compared to age-matched controls. The authors also reported an OR of 10.7 for men who reported Viagra use and a history of myocardial infarction (MI) and an OR of 6.9 for men who reported Viagra use and a history of hypertension. More recently Margo et al. reported a relative risk of nonarteritic ischemic optic neuropathy (NION) and possible NION for men prescribed phosphodiesterase (PDE)-5 inhibitors of 1.10 (NION RR 1.02; possible NION 1.34). Thus, men who were dispensed PDE-5 inhibitors were 10% more likely to have a diagnosis or possible diagnosis of NION compared to those who had not been dispensed these medications.

II.b. Consistency with Other Knowledge: Consistency refers to the fact that despite differences in study design and/or study population, there is uniformity across study results. The published, peer-reviewed studies on the association between Viagra and NAION are consistent demonstrating an overall increased risk of between 10- and 75-percent. The consistency of the stronger associations among those with a history of myocardial infarction (MI) or hypertension observed in the McGwin et al. study cannot be evaluated because no such studies have evaluated this relationship to date.

II.c. Specificity: Specificity refers to an association being limited to a particular exposure-disease relationship. This criterion is not considered necessary by epidemiologists in recognition of the fact that most, if not all, diseases are multi-factorial. And while the epidemiology of NAION is not well developed, a number of hypothesized risk factors have been suggested, though none have been associated with the disease in a conclusive manner.

II.d. Temporal Relationship: In order for a given exposure to be causally related to a given disease, it must be demonstrated that the exposure preceded the disease. In the McGwin et al. study the authors only evaluated Viagra use that occurred prior to NAION diagnosis date; however, due to the study design such a temporal relationship could not be evaluated in the Margo et al. study.

In the field of epidemiology, there is a hierarchy of study designs with cohort studies generally considered to provide more substantial evidence for an association than cross-sectional studies. At the bottom of this hierarchy are case-reports and series, reflecting their inability to test scientific hypotheses. However, such reports can provide important insight into the etiology of a hypothesized exposure-disease relationship. There have been a number of published case-reports and -series of NAION occurring soon (i.e., minutes to hours) after the use of Viagra. While these cases cannot be definitively linked to Viagra use nor do they provide a quantifiable measure of disease risk associated with Viagra use, they shed light on the issue of temporality that must be considered in conjunction with other epidemiologic research. In fact, the Pfizer documentation, it is stated that, based upon such case reports and series, an association between Viagra and NAION cannot be fully or totally ruled out.

II.e. Biological Gradient: This criterion refers to a dose-response relationship, that is, the more intense of the exposure, the greater the risk of disease. As with specificity, this criterion makes an important assumption as to the etiology of the exposure-disease relationship in question. Indeed, there are several well-documented exposure-disease relationships wherein such dose-response relationships do not exist. Thus, a dose-response relationship is not necessary to infer causation. That being said, the epidemiologic research to date has not evaluated the issue of dose-response.

II.f. Biologic Plausibility: That an exposure-disease relationship can, for example, be consistently documented in numerous epidemiologic studies is important; however, it is equally important that such a relationship be biologically plausible. It is important to note

that observations reported in epidemiologic studies have not always had a biologic rationale at the time they were reported, yet were subsequently shown to be correct.

With respect to Viagra's potential impact on the eye, visual adverse events have been reported in Viagra clinical trials. However, these were reported to be transient effects and uncommon. With respect to the specific association between Viagra and NAION, there are several plausible mechanisms that support this relationship, including hypo-perfusion and compartment syndrome. With respect to the former, Viagra has a mild systemic hypotensive effect and, in some at risk individuals, this could reduce perfusion of the optic nerve head resulting in ischemia and ultimately NAION. The mild vasodilatation of ocular blood vessels associated with Viagra could cause optic nerve fiber crowding thereby impacting blood flow to the optic nerve resulting in a compartment syndrome. A number of other potential mechanisms have also been discussed.

II.g. Biologic Coherence: This refers to the fact that the cause and effect interpretation should not seriously conflict with the generally known facts regarding the natural history and biology of the disease. With respect to the peer-reviewed, published epidemiologic evidence, there is no conflict in this regard.

II.h. Experimental Evidence: There is no direct experimental evidence regarding the association between Viagra and NAION in the form of human clinical trials or laboratory experiments involving animals.

II.i. Analogy: Analogy refers to the situation wherein there are other, similar, known relationships. There have been case-reports of the occurrence of NAION following the use of tadalafil (Cialis), another PDE-5 inhibitor and McGwin et al. reported an OR of 1.82 for the association between Cialis use and NAION.

III. Sildenafil Citrate (Viagra) and Nonarteritic Anterior Ischemic Optic Neuropathy (NAION): Additional Considerations

Pfizer has taken a particular stance regarding the association between Viagra and NAION; specifically, that there is no increased incidence of NAION in men who took Viagra for the treatment of erectile dysfunction (ED). Their expert reviewers have provided a broader conclusion; that is, there does not appear to be any evidence to suggest an association between sildenafil therapy and NAION. Moreover, though the FDA has recommended that Pfizer conduct a case-control study on this association, the company has concluded that study an endeavor would be infeasible. They further conclude that the results of such a study would not contribute additional understanding beyond what it is already known. They have provided a variety of evidence in support of their position regarding the current state of knowledge on the association between Viagra and NAION as well as their willingness to pursue epidemiologic studies on the topic. Thus, it is important to review this evidence.

III.a. Results from Pfizer-sponsored Research: According to Pfizer documentation and a recently published manuscript, a review of 103 double-blind or open-label trials of

Viagra conducted between 1993 and 2003, revealed no cases of NAION. This data represents over 13,400 men with ED and 13,300 patient years of observation.

Additionally, based upon data from the International Men's Health Study (IMHS), no cases of NAION were observed among 3,813 men during 2,935 patient-years of follow-up.

And finally, in a study conducted in the United Kingdom (i.e., the PEM study) one case of NAION was observed among 28,074 patients during 35,500 patient years of follow-up. It is based upon this study that Pfizer relies when concluding that the rate of NAION is similar to that in the general population (i.e., 2.5-11.8 per 100,000).

III.a.1. Critique of Pfizer Evidence

There are a number of issues to consider when weighing the strength of the evidence described above. First, if one assumes that the incidence of NAION is 2.52 per 100,000 then in their review of 103 trials one would expect to have observed less than 1 case of NAION. Even with a moderate to strong association, the expected number of cases is quite small thus calling into question the statistical power associated with this evidence. The same critique can be made of their analysis of data from the IMHS and the PEM study. This is an important consideration as Pfizer raises the same issue of limited statistical power when discounting the results of the McGwin et al. study.

Second, among the other limitations noted by Pfizer of the McGwin et al. study is the issue of case definition. In fact, they also cite this as a reason why the design of the FDA-requested case-control study, or any other study for that matter, is not feasible. This raises the question as to identification of NAION cases in the three above-mentioned analyses conducted by the company. If case definition is such a thorny issue that it precludes even properly designing a study on this topic, how then how should their own evidence for lack of an association be interpreted? In particular the IMHS study wherein health status was initially ascertained via self-report.

Third, to what extent was the design of the evaluated data adequate to truly evaluate the relationship in question? Specifically, was this data adequate to address the temporal relationship between Viagra use and NAION occurrence? Again, among the many deficiencies noted by Pfizer is limited insight into the time course of the ischemic event. Thus, despite not seeing any NAION events, would these studies have been able to address this issue had they been observed?

Fourth, having observed one case of NAION in the PEM study, Pfizer concludes that the incidence rate in this study is consistent with that in the general population cited two published studies wherein NAION incidence was reported. However, in citing reasons why the design of proposed studies and the interpretation of existing ones is problematic, Pfizer strongly criticizes the same

two studies they use to conclude that the rate in the PEM study is equivalent to that in the general population. Thus, in addition to their calculated incidence rate being questionable, such likely justifiable criticism of the true incidence of the disease raises significant questions regarding their conclusion.

And finally, Pfizer cites the imprecision of the estimates reported in the McGwin et al. study as a significant limitation of this work. However, based upon the analysis of the PEM data (1 case per 35,500 patient years of follow-up), the incidence rate of 2.8 per 100,000 would have a 95% confidence interval of 0.071 to 15.65. Again, it is not clear why Pfizer's criticism of the peer-reviewed literature would not also be reflected in their work.

III.b. Response to Criticisms of the McGwin et al. Study: Pfizer has identified many limitations of the study conducted by McGwin et al. on the association between Viagra and NAION, several of which were also noted by the authors and deemed inconsequential to the study's conclusions. Among the other limitations was:

III.b.1. Timing

Though the analysis was limited to ED medication use that occurred prior to NAION diagnosis there was no information presented as to the exact timing of these events. Since the study was not specifically designed to address this issue, this level of detail was not sought; however, in such retrospective studies the ability to collect such information is often tenuous.

III.b.2. Statistical Analysis

The results of study suggest that the association between ED medications and NAION is dependent upon the presence of MI and hypertension. The study is criticized for not having explicitly proposed these analyses. Given the published case reports and series, that co-morbid cardiovascular disease might play a role is reasonable. Moreover, given the difference in the prevalence of the conditions between the cases and controls, an analysis exploring their confounding and/or modifying effect is also reasonable. Finally, the basis for giving less credibility to unplanned analyses is unclear.

III.b.3. Potential Confounding

It is suggested that the difference in the prevalence of MI between cases and controls is the solely responsible for the association reported in Table 3 of the paper. The rationale for this conclusion is not clear. The results presented in Table 3 provide separate estimates according to both ED medication use and MI history. The objective of such an analysis is to characterize the potentially modifying effect of MI.

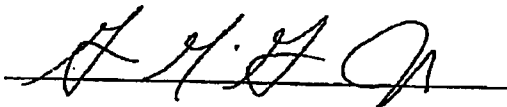
It is important to note that despite its acknowledged limitations an evaluation of

the McGwin et al. study by Pfizer's own advisory board fails to identify any fatal flaws that would completely call into question the observed results. While these limitations perhaps detract from the impact of the conclusions, there is little reason to suggest that the results do not support them. Moreover, even in the aggregate the gravity of the reported limitations is unlikely sufficient to explain the large association reported in the study. And perhaps more importantly the Pfizer advisory board, as well as the FDA, recommended that Pfizer conduct a case-control study featuring many of the study design elements of the McGwin et al. study.

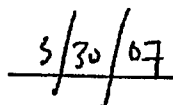
IV. Summary and Conclusion

In summary, the available peer-review, published epidemiologic literature provides sufficient evidence that Viagra can cause of NAION and other ocular vascular disorders. The non-peer reviewed evidence offered by Pfizer for the lack of an association between Viagra and NAION is significantly flawed and seriously calls into question their conclusion that the incidence of NAION among men using Viagra is similar to that in the general population. Many of the deficiencies in our understanding of the epidemiology of NAION used by the company to dismiss existing research and the feasibility of future work is seemingly ignored when presenting their own evidence for lack of an association. Finally, the FDA and members of Pfizer's own advisory board advocated many aspects of the McGwin et al. study and recommended that the company conduct a similar study. This not only reflects the appropriateness and strength of the case-control design for evaluated the association between Viagra and NAION but also the importance of McGwin et al.'s findings.

Thus, in conclusion, to a reasonable degree of scientific certainty, it is my opinion that Viagra can cause NAION and other ocular vascular disorders.



Gerald McGwin, Jr., M.S., Ph.D.



Date

CURRICULUM VITAE

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15k (55:18, 01/2007)
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EDUCATION:

University of Vermont

Bachelor of Science in Human Development and Family Studies – 1993.

Harvard University
Master of Science in Health and Social Behavior – 1995.

University of Alabama at Birmingham
Doctor of Philosophy in Epidemiology – 1998.

**ACADEMIC
APPOINTMENTS:**

Ph.D. Program Director
Department of Epidemiology
School of Public Health
University of Alabama at Birmingham.
June 2005 to present.

Associate Professor of Epidemiology
Department of Epidemiology
School of Public Health
University of Alabama at Birmingham.
January 2003 to present.

Assistant Professor of Ophthalmology
Department of Ophthalmology
School of Medicine
University of Alabama at Birmingham
January 2003 to present.

Assistant Professor of Epidemiology
Department of Epidemiology
School of Public Health
University of Alabama at Birmingham.
September 1998 to December 2002.

Assistant Professor of Surgery
Section of Trauma, Burns, and Surgical Critical Care
Division of General Surgery
Department of Surgery
School of Medicine
University of Alabama at Birmingham
September 1998 to present.

Assistant Professor of Ophthalmology
Department of Ophthalmology
School of Medicine

University of Alabama at Birmingham
February 2001 to December 2002.

Associate Director
Center for Injury Sciences at the University of Alabama at
Birmingham
January 2001 to present.

Associate Director
Clinical Research Unit
Department of Ophthalmology
School of Medicine
University of Alabama at Birmingham
January 2001 to present.

Scientist
Center for Aging, University of Alabama at Birmingham,
Birmingham, Alabama.
September 1999 to present.

Epidemiologist
Mercedes-Benz Crash Injury Research Engineering
Network (CIREN) Center, University of Alabama at
Birmingham, Birmingham, Alabama.
September 1999 to present.

VISTING PROFESSORSHIPS:

Injury Control Research Center, Harvard School of Public
Health – April 2002

Department of Public Health Sciences, Division of
Epidemiology, University of California – Davis, February
2003

Department of Ophthalmology, University of California –
San Francisco, March 2006

Department of Geriatrics, University of California – San
Francisco, October 2006

COUNCILS/COMMITTEES:

Member, Birmingham Regional Emergency Medical
Services System Quality Assurance Committee
August 1999 to 2002.

Consultant, State Emergency Medical Control Committee

Alabama Department of Public Health
January 1999 to 2003.

Chair, Alabama Trauma Registry Task Force
Alabama Department of Public Health
March 2001 to 2003.

Member, Review Committee
American Medical Association/National Highway Traffic
Safety Administration
*Physician's Guide to Assessing and Counseling Older
Drivers*
January 2003 to December 2004

Member, Committee for the Safe Mobility of Older Persons
Transportation Research Board
June 2003 to present

Member, Search Committee
Various faculty positions
UAB School of Public Health
UAB School of Medicine
January 2004 to present

Member, Faculty Affairs Committee
School of Public Health
University of Alabama at Birmingham
March 2004 to 2006

Member, Scientific Advisory Board
Restore Effective Survival in Shock (Clinical Trial)
Naval Medical Research Center
January 2005 to present

Member, Epidemiology Training Committee
School of Public Health
University of Alabama at Birmingham
January 2005 to present

Member, Search Committee
UAB GCRC Informatics Core Director
January 2005 to December 2005

Member, Search Committee
Associate Dean, UAB School of Public Health
December 2006 to present

EDITORIAL SERVICE:

Reviewer – *Accident Analysis and Prevention*
January 1999 to present.

Reviewer – *American Journal of Epidemiology*
January 2000 to present.

Reviewer – *American Journal of Public Health*
January 2002 to present

Reviewer – *Epidemiology*
February 2002 to present.

Reviewer – *Injury Prevention*
July 2002 to present.

Reviewer – *Investigative Ophthalmology and Vision
Science*
July 2002 to present.

Reviewer – *JAMA*
July 2002 to present.

Reviewer – *Journal of Vision*
July 2002 to present.

Reviewer – *Archives of Ophthalmology*
August 2002 to present.

Reviewer – *Optometry and Vision Science*
January 2003 to present.

Reviewer – *American Journal of Preventive Medicine*
January 2003 to present.

Reviewer – *Shock*
January 2003 to present

Reviewer – *Occupational and Environmental Medicine*
January 2004 to present

Reviewer – *Obesity Research*
May 2004 to present

Reviewer – *Journal of Women's Health*

May 2004 to present

Associate Editor – *American Journal of Epidemiology*
November 2004 to present

GRANT REVIEWER:

Special Emphasis Panel, National Eye Institute, NIH; 2005, 2006

James and Esther King Biomedical Research Program,
Florida Department of Public Health; 2007

Bankhead-Coley Cancer Research Program, Florida
Department of Public Health; 2007

AAA (American Automobile Foundation) Foundation for
Traffic Safety, Washington, D.C.; 2006, 2007

Intramural Grant Reviewer, UAB Center for Aging; 2004, 2005

Grant Reviewer, National Institute of Occupational Safety
and Health, Centers for Disease Control and Prevention,
2003, 2004

Scientific Merit Review, Department of Veteran Affairs'
Rehabilitation Research & Development Service,
Washington, D.C.; 2004, 2006

Grant Reviewer, Canadian Institutes of Health Research,
2004

Grant Reviewer, (Ireland) Health Research Board; 2003

TEACHING EXPERIENCE:

Instructor
Introduction to SAS
Department of Epidemiology, School of Public Health,
University of Alabama at Birmingham
1998 to 2003.

Instructor
Analysis and Presentation of Epidemiologic Data
Department of Epidemiology, School of Public Health,
University of Alabama at Birmingham
1999 to present.

Instructor
The Analysis of Case-Control Studies
Department of Epidemiology, School of Public Health,
University of Alabama at Birmingham
2000 to present.

Instructor
Master's Seminar
Department of Epidemiology, School of Public Health,
University of Alabama at Birmingham
2001 to present.

Instructor
Introduction of Health and Human Disease
School of Health-Related Professions, University of
Alabama at Birmingham
2002 to present.

Instructor
The Analysis of Cohort Studies
Department of Epidemiology, School of Public Health,
University of Alabama at Birmingham
2003 to present.

GRANT SUPPORT:

P50 AR45231 07/01/1998 – 06/30/2003
NIH / NIAMS
Specialized Center of Research in SLE
Role: Co-Investigator

03/11/1999 – 09/30/2004
FHWA / DOT
UAB Trauma Care Center
Role: Co-Investigator

04/20/1999 – 04/20/2004
Mercedes-Benz
Crash Injury Research and Engineering Network Center
Role: Co-Investigator

DTFH61-99-X-00039 06/01/1999 – 05/31/2004
FHWA / DOT
The Study of Advanced Trauma Care

Role: Co-Investigator

07/15/1999 – 12/31/2002

FHWA / DOT

Development of a Model State Brain Injury Program

Role: Co-Investigator

R01 AR47799

09/30/2000 – 08/31/2004

NIH / NIAMS

Genetic Polymorphism in Wegener's Granulomatosis

Role: Co-Investigator

000-154-101

08/01/2001 - 07/31/2004

Alabama Eye Institute

Multivariate Confirmatory Analysis of Psychophysical and
Structural Parameters in Glaucomatous Optic Neuropathy

Role: Co-Investigator

R01AG04212-16

01/15/2001 – 12/31/2005

NIH / NIA

Visual Dysfunction and Aging: Underlying Mechanisms

Role: Co-Investigator

12/01/2001 – 11/01/2002

HHS / PHS / CDC

Older Driver Cohort Study

Role: P.I.

ITS-AL01 (900)

03/18/2002 – 03/17/2004

FHWA / DOT

Automated Crash Notification (ACN) System Integration

Role: Co-Investigator

R21 EY140711

04/01/2002 – 03/31/2007

NIH / NEI

Clinical Vision Research Unit at UAB

Role: Co-Investigator

U01HD42687-01

09/05/2002 – 06/30/2007

NIH / NICHD

Multi-center TBI Clinical Trials Network

Role: Co-Investigator

P50AG11684-11

09/15/2002 – 01/01/2008

NIA / HHS / PHS / NIH

Enhancing Mobility in the Elderly – Management Core

Role: Co-Investigator

R01 OH07564-02 09/30/2002 – 09/29/2004
NIOSH / HHS / PHS / CDC
Extended Work Schedules and Health Outcomes in the US
Role: P.I.

R01 AR42503-10S2 08/31/2003 – 09/01/2007
NIH / NIAMS
Outcome of SLE in Minorities - Nature vs. Nurture
Role: Co-Investigator

R01AG021958-01 09/01/2003 – 08/31/2008
NIA / HHS / PHS / NIH
Predicting Long-Term Mobility Outcomes for Older Adults
Role: Co-Investigator

U01AG14289-05S3 09/30/2003 – 06/30/2004
NIH / NIA
Cognitive Training & Everyday Competence in the Elderly
Role: Co-Investigator

R01EY015559-04 09/30/2003 – 08/31/2007
NIH / NEI / Duke University
Improving the Quality of Diabetes Eye Care
Role: P.I. (Subcontract)

P30AG022838 09/30/2003 – 09/29/2004
NIH / NIA
Center for Translational Research on Aging and Mobility
Role: Co-Investigator

000177049 04/02/2004 – 04/01/2008
Veteran's Administration IPA.
Enhancing Mobility in the Visually Impaired
Role: P.I.

000177050 04/02/2004 – 04/01/2008
Veteran's Administration IPA.
The Impact of Blind Rehab on Quality of Life in Visually
Impaired Veterans
Role: P.I.

06/15/2004 – 06/14/2005
Insurance Institute for Highway Safety
Impact of Florida's Mandatory Vision Screening Law for
Divers 80 Years and Over.
Role: Co-Investigator

C10119098 11/02/2004 – 11/01/2007
HRSA / ADPH
Patient Care Report (PCR) Database Management
Role: Co-Investigator

05/23/2005 – 01/31/2006
Evaluation of the AARP Driver Safety Program in Florida
and New York
AARP Andrus Foundation
Role: Co-Investigator

03/01/2006 – 02/28/2007
Prevent Blindness America
Vision Impairment and Access to Eye Care Module in the
Alabama Behavioral Risk Factor Surveillance System
Role: P.I.

05/01/2006 – 06/15/2008
Medication Use and Motor Vehicle Collisions Among
Older Drivers
AAA Foundation for Traffic Safety
Role: P.I.

R21EY016801-01A1 04/01/2006 – 03/31/2008
Planning a Clinical Trial on Low Vision Rehabilitation
NIH / NEI
Role: Co-Investigator

SUBMITTED GRANTS:

Statins and Age-Related Macular Degeneration
NIH / NEI
Submitted: 10/01/2004
Role: P.I.
Status: *Not funded*

ARMD Research Partnership of Alabama
Eyesight Foundation of Alabama
Submitted: 01/31/2004
Role: P.I.
Status: *Not funded*

Expanding Quality Care for Glaucoma through Provider-
Patient Partnership
NIH / NEI
Submitted: 06/01/2006

Role: P.I. (Subcontract)
Status: *Pending*

Older drivers: An Evidence-Basis for Licensure Standards
NIH / NIA
Submitted: 07/01/2006
Role: Co-Investigator
Status: *Pending*

Protective Eyewear and Work-Related Eye Injury: A Case-Crossover Study
Eyesight Foundation of Alabama
Submitted: 12/01/2006
Role: P.I.
Status: *Pending*

Project *inCHARGE*: Increasing the Rate of Comprehensive Eye Care Utilization by Older African Americans through a Community-Based Eye Health Education Program
UAB Center for the Study of Community Health
Submitted: 01/15/2007
Role: P.I.
Status: *Pending*

Aging and ARM: Dark Adaptation Impairment
NIH / NEI
Submitted: 01/15/2007
Role: Co-Investigator
Status: *Pending*

BIBLIOGRAPHY:

BOOK CHAPTERS:

McGwin G, Owsley C. Statins and age-related maculopathy. In: Tombran-Tink J and Barnstable CJ (Editors) Retinal Degenerations: Biology, Diagnostics, and Therapeutics. Totowa, NJ: The Humana Press; 2006.

MANUSCRIPTS:

Published:

1. McGwin G, Roseman JM, Owsley C. Epidemiology and the internet [letter]. *Epidemiology* 1997;8(4):465.

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